

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

## **MEMORANDUM**:

From: Kevin Sweeney, Senior Entomologist

**Date**: August 21, 2012

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD

DP barcode: 404590 Decision no.: 463791 Submission no: 915257

Action code: R301 (These normally don't require an efficacy review)

Product Name: Hartz Reference #141 EPA Reg. No or File Symbol: 2596-RTU Formulation Type: RTU cat/kitten spot-on

Ingredients statement from the label with PC codes included: 40% etofenprox (PC code:

128965) and 3.6% s-methoprene (PC code: 105402)

Use pattern: spot-on to cats/kittens

Application rates of product/active ingredient:

1 ml for cats/kittens under 5 lbs 1.8 ml for cats 5 lbs and over

OCSPP Guideline: 810.3300

**I. Action Requested:** "me-too" product selectively citing efficacy data. Please review selective citations for completeness.

**II. Background**: This product is citing EPA Reg. No. 2724-504 as product that is substantially similar to the pending product. Efficacy data were cited under the selective method of support.

## III. Study Reviews:

The data matrix for the new product cited the following MRIDs:

46513411

46513412

46513414

46513415

EPA also reviewed the following MRIDs in support of EPA Reg. No. 2724-504 and these are relevant to fulfilling the efficacy data requirements for the new product:

46513410

48561001

These were not cited on the data matrix for the new product and must be added.

## **Entomologist's Recommendations:**

- 1. Provided the registrant of the new product submits a revised data matrix that includes the 2 additional MRIDs, the efficacy requirements for this product are fulfilled.
- 2. Regarding labeling, I recommend the reviewer:
  - Compare the new product label to the most recently accepted label for EPA Reg. No. 2724-504.
  - Accept claims and directions for use that appear on the label for EPA Reg. No. 2724-504.
  - Request removal of claims and directions for use that were not approved/authorized on the EPA Reg. No. 2724-504 label. Minor wording changes in the directions for use are acceptable but new claims should not be accepted.